K092257
1 of 2

ATTACHMENT 2

510(k) SUMMARY

510(k) Owner: Fidia Advanced Biopolymers S.r.l.
Via Ponte dell Fabbrica 3/B
35031 Abano Terme
PADOVA, ITALY

JAN 2 6 2010

Contact: Dr. Adriano Zanotti
Regulatory Affairs
Phone: +39-049-82 32 650
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Date Summary Prepared: December 10, 2009

Device:
Trade Name: JALOSKIN
Common/Classification Name: Wound Dressing
Product Code FRO
Classification: Unclassified

Predicate Devices:
HYALOMATRIX™ KC
Fidia Advanced Biopolymers S.r.l.
K001508

HYALOMATRIX PA®
Fidia Advanced Biopolymers S.r.l.
K073251

Device Description: JALOSKIN is a semi-permeable, transparent film dressing, composed of HYAFF® 11, a benzyl ester of hyaluronic acid. The hyaluronic acid is derived from bacterial fermentation.

Intended Use: JALOSKIN is indicated for the management of superficial moderately exuding wounds including pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, skin tears) and first and second degree burns.

Technological Characteristics:	JALOSKIN is substantially equivalent to the predicate devices with regard the intended use and/or technological characteristics. HYAFF 11 has been used in legally marketed predicate devices, and no new questions of safety or effectiveness are presented by the technological differences between JALOSKIN and its predicate devices.
Biocompatibility Data	*In vitro* cytotoxicity studies and a hemolysis study in rabbits demonstrate that HYAFF films are neither cytogenic nor hemolytic. Acute oral and dermal toxicity studies on HYAFF powder in rats and indicate that the lethal dose of HYAFF 11 is greater than 5,000 mg/kg and 2,000 mg/kg, respectively. Irritation studies in rabbits demonstrate that HYAFF 11 powder is not an ocular or dermal irritant, and a sensitization study in guinea pigs provides evidence for the lack of a sensitizing effect. No evidence of genotoxicity was observed in three *in vitro* assays or one *in vivo* study in mice. An implantation study of up to 1 year in rats found no evidence of treatment-related toxicity, and demonstrated that the HYAFF film was degraded within 4 months.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Fidia Advanced Biopolymers S.r.l.
% Morgan, Lewis, & Bocklus LLP
Sharon A. Segal, Ph.D.
1111 Pennsylvania Avenue, Northwest
Washington, District of Columbia 20004

JAN 2 6 2010

Re: K092257
Trade/Device Name: JALOSKIN
Regulatory Class: Unclassified
Product Code: FRO
Dated: December 10, 2009
Received: December 10, 2009

Dear Dr. Segal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 1

Indications for Use

510(k) Number (if known): K092257

Device Name: JALOSKIN

Indications for Use: JALOSKIN is indicated for the management of superficial moderately exuding wounds including pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, skin tears) and first and second degree burns.

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K092257

Prescription Use ✓ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)